

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising an alpha 1-antitrypsin (AAT), a stabilizing carbohydrate, a surfactant and an antioxidant, wherein the AAT is a native AAT, a recombinant AAT, or an AAT variant.
2. The composition of claim 1, wherein the composition is in a form suitable for administration to a patient via inhalation therapy.
3. The composition of claim 2, wherein the composition is formulated as a powder.
4. The composition of claim 2, wherein the composition is formulated as a liquid that can be nebulized.
5. The composition of claim 1, wherein the AAT is a native AAT.
6. The composition of claim 1, wherein the AAT is a recombinant AAT.
7. The composition of claim 1, wherein the AAT is an AAT variant.
8. The composition of claim 1, wherein the AAT is glycosylated.
9. The composition of claim 1, wherein the AAT is unglycosylated.
10. The composition of claim 1, wherein the stabilizing carbohydrate is selected from the group consisting of lactose, sucrose, trehalose, raffinose, maltodextrin and mannitol.
11. The composition of claim 10, wherein the stabilizing carbohydrate is trehalose.
12. The composition of claim 1, wherein the antioxidant is selected from the group consisting of methionine, glutathione, cysteine, ascorbic acid and N-acetyl cysteine.
13. The composition of claim 3, wherein the AAT, carbohydrate, surfactant and antioxidant are present in amounts such that if the powder is solubilized in aqueous solution for administration to a patient the AAT concentration is 1 -100 mg/ml, the carbohydrate concentration is 1-5% (w/v), the surfactant concentration is 0.01-0.5% (w/v), and the antioxidant concentration is 1-10 mM.
14. The composition of claim 13, wherein the AAT concentration is 10-50 mg/ml.
15. The composition of claim 4, wherein the AAT concentration is 1 -100mg/ml, the carbohydrate concentration is 1-5% (w/v), the surfactant concentration is 0.01-0.5% (w/v), and the antioxidant concentration is 1-10 mM.

16. The composition of claim 15, wherein the AAT concentration is 10-50 mg/ml.
17. The composition of claim 3, further comprising a buffer and wherein.
 - (a) the carbohydrate is trehalose and the antioxidant is methionine; and
 - (b) the AAT, trehalose, surfactant and methionine are present in amounts such that if the powder is solubilized in aqueous solution for administration to a patient (i) the AAT concentration is 10-50 mg/ml, (ii) the trehalose concentration is 10-50 mg/ml, (iii) the surfactant concentration is 0.01-0.5% (w/v), and (iv) the methionine concentration is 1-10 mM.
18. The composition of claim 4, further comprising a buffer and wherein
 - (a) the AAT concentration is 10-50 mg/ml;
 - (b) the carbohydrate is trehalose and its concentration is 10-50 mg/ml;
 - (c) the surfactant concentration is 0.01-0.5% (w/v); and
 - (d) the antioxidant is methionine and its concentration is 1-10 mM.
19. A pharmaceutical composition, comprising a recombinant alpha 1-antitrypsin (AAT), a stabilizing carbohydrate and at least one additional stabilizing agent selected from the group consisting of a surfactant and an antioxidant, wherein the AAT/carbohydrate ratio (weight:weight) is 1:1 to 5:1, and further wherein the AAT is a native AAT, a recombinant AAT, or an AAT variant.
20. The composition of claim 19, wherein the ratio is 1:1 to 2:1.
21. The composition of claim 19, wherein the stabilizing carbohydrate is trehalose.
22. The composition of claim 19, wherein the composition comprises the surfactant.
23. The composition of claim 19, wherein the composition comprises the antioxidant.
24. The composition of claim 19, wherein the composition comprises both the surfactant and the antioxidant.
25. The composition of claim 24, wherein the surfactant is Polysorbate 80 and the antioxidant is methionine.
26. The composition of claim 19, wherein the composition is formulated as a solid.
27. The composition of claim 19, wherein the composition is formulated as a liquid.

28. The composition of claim 1, wherein the AAT is a native AAT.
29. The composition of claim 1, wherein the AAT is a recombinant AAT.
30. The composition of claim 1, wherein the AAT is an AAT variant.
31. The composition of claim 1, wherein the AAT is glycosylated.
32. The composition of claim 1, wherein the AAT is unglycosylated.

33. A method for treating a pulmonary disease associated with alpha 1-antitrypsin (AAT) deficiency, the method comprising administering to the lungs of a patient a pharmaceutical composition that comprises an effective amount of AAT, a stabilizing carbohydrate, a surfactant and an antioxidant, wherein the AAT is a native AAT, a recombinant AAT, or an AAT variant.

34. The method of claim 33, wherein the composition is administered by inhalation.
35. The method of claim 34, wherein the composition is a solid and is administered by converting the solid into an aerosol for inhalation by the patient.
36. The method of claim 34, wherein the composition is a liquid and is administered by nebulizing the liquid for inhalation by the patient.
37. The method of claim 33, wherein the disease is a pulmonary disease associated with the activity of elastase, cathepsin G and/or proteinase 3.
38. The method of claim 37, wherein the disease is emphysema.
39. The method of claim 33, wherein the disease is a pulmonary inflammatory disease associated with activation of neutrophils, mast cells or T-cells.
40. The method of claim 39, wherein the disease is asthma.
41. The method of claim 39, wherein the disease is adult respiratory distress syndrome, neonatal respiratory distress syndrome or sepsis syndrome.
42. The method of claim 33, wherein the patient is susceptible to the disease and the pharmaceutical composition is administered in a prophylactically effective amount.
43. The method of claim 33, wherein the patient has the disease and the pharmaceutical composition is administered in a therapeutically effective amount.

44. The method of claim 33, wherein the AAT is a native occurring AAT.
45. The method of claim 33, wherein the AAT is a recombinant AAT.
46. The method of claim 33, wherein the AAT is an AAT variant.
47. The method of claim 33, wherein the AAT is glycosylated .
48. The method of claim 33, wherein the AAT is unglycosylated.
49. The method of claim 33, wherein the stabilizing carbohydrate is trehalose.
50. The method of claim 33, wherein the antioxidant is selected from the group consisting of methionine, glutathione, cysteine, ascorbic acid and N-acetyl cysteine.

51. The method of claim 35, wherein the AAT, carbohydrate, surfactant and antioxidant are present in amounts such that if the powder is solubilized in aqueous solution for administration to a patient the AAT concentration is 1 -100 mg/ml, the carbohydrate concentration is 1-5% (w/v), the surfactant concentration is 0.01-0.5% (w/v), and the antioxidant concentration is 1-10 mM.

52. The method of claim 51, wherein the AAT concentration is 10-50 mg/ml.
53. The method of claim 36, wherein the AAT concentration is 1 -100 mg/ml, the carbohydrate concentration is 1-5% (w/v), the surfactant concentration is 0.01-0.5% (w/v), and the antioxidant concentration is 1-10 mM.
54. The method of claim 53, wherein the AAT concentration is 10-50 mg/ml.
55. The method of claim 35, further comprising a buffer and wherein
 - (a) the carbohydrate is trehalose and the antioxidant is methionine; and
 - (b) the AAT, trehalose, surfactant and methionine are present in amounts such that if the powder is solubilized in aqueous solution for administration to a patient (i) the AAT concentration is 10-50 mg/ml, (ii) the trehalose concentration is 10-50 mg/ml, (iii) the surfactant concentration is 0.01-0.5% (w/v), and (iv) the methionine concentration is 1-10 mM.
56. The method of claim 36, further comprising a buffer and wherein
 - (a) the AAT concentration is 10-50 mg/ml;
 - (b) the carbohydrate is trehalose and its concentration is 10-50 mg/ml;
 - (c) the surfactant concentration is 0.01-0.5% (w/v); and
 - (d) the antioxidant is methionine and its concentration is 1-10 mM.
57. A method for treating a pulmonary disease associated with alpha 1-antitrypsin (AAT) deficiency, the method comprising administering to the lungs of a patient a

pharmaceutical composition that comprises unglycosylated recombinant AAT, a stabilizing carbohydrate and at least one additional stabilizing agent selected from the group consisting of a surfactant and an antioxidant, wherein the AAT/carbohydrate ratio is 1:1 to 5:1.

58. The method of claim 57, wherein the ratio is 1:1-2:1.
59. The method of claim 57, wherein the composition is administered by inhalation.
60. The method of claim 59, wherein the composition is a solid and is administered by converting the solid into an aerosol for inhalation by the patient.
61. The method of claim 59, wherein the composition is a liquid and is administered by nebulizing the liquid for inhalation by the patient.
62. The method of claim 59, wherein the disease is a pulmonary disease associated with the activity of elastase, cathepsin G and/or proteinase 3.
63. The method of claim 62, wherein the disease is emphysema.
64. The method of claim 59, wherein the disease is a pulmonary inflammatory disease associated with activation of neutrophils, mast cells or T-cells.
65. The method of claim 64, wherein the disease is asthma.
66. The method of claim 65, wherein the disease is adult respiratory distress syndrome, neonatal respiratory distress syndrome or sepsis syndrome.
67. The method of claim 59, wherein the stabilizing carbohydrate is trehalose.
68. The method of claim 59, wherein the composition comprises both the surfactant and the antioxidant and the surfactant is Polysorbate 80 and the antioxidant is methionine.